REMARKS

Claims 1-10, 12-19, and 22-28 have been amended to add either "A", "An", or "The" to recite, for instance "A method according to . . .".

Claim 1 has been amended to recite "wherein the antibody is an IgG1 antibody wherein the constant region of said IgG1 antibody comprises the constant region of an IgG2a subtype amino acid". Support for the amendment is found in the specification page 14, lines 14-19.

Claim 9 has been amended to recite "Lewis-y". Support for the amendment is found in claim 30 and in the specification at page 4, line 37. Claim 9 has further been amended to depend from claim "2 or 3" providing antecedent basis for the term "the antigen". To reflect U.S. format for claim 9, dependent claims 31, 32, and 33 have been added.

Claim 12 has been amended to recite "CH1". Support for the amendment is found in the specification at page 14, line 17. Claim 12 has further been amended to comply with U.S. practice.

Claim 30 has been amended to conform with U.S. patent practice.

No new matter has been added.

Specification Objections

A substitute specification is provided herein. Both a marked up copy and a clean copy have been provided. No new matter has been added.

The references to □-Gal epitopes, "□Gal□1,3GALß1, 4GlcNAc-R" and "□–gal eptope" and "□1,3, Galactosyltansferase" on page 9, lines 22-25 have been changed and replaced with "αGalα1,3Galß1, 4GlcNAc-R" and "α–gal epitope" and "α1,3, Galactosyltansferase". Support for the amendment is found on page 12, lines 16 and 33, which recite "alpha 1-3-galosyl-epitope". No new matter has been added.

The reference to "Maxisorp□" and "Novex □" on page 23 as originally filed, have been amended to read "Maxisorp™" and "Novex™". Applicants submit that the symbol from the word processing document did not transfer for these references, and that one skilled in the art would recognize a trademarked item.

The Examiner objects to "□ 215 and □ 280 nm". (Specification as filed page 24, line 23). Applicants submit that the were intended to be "λ 215 nm and λ 280 nm" to denote the wavelengths at which peptide and disulfide bonds absorb, as one skilled in the art would know from the context. Thus Applicants have amended the specification to recite "λ 215 nm and λ 280 nm".

The specification now cross references priority documents as disclosed in the original PCT filing and WO publication.

The Brief Description of the drawings section has been moved.

The Abstract of Disclosure now appears as a separate sheet to the specification.

SEQ ID NO have been added to the figures, as disclosed in the priority publication WO 2004/091655 A2.

All of these changes are reflected in the substitute specification. No new matter has been added.

Claim Objections

Claims 5, 9, and 30 are objected to because the spelling of the carbohydrate "Lewis-y" and "Lewis Y" are inconsistent. Applicants have amended the claims to make them consistent. Applicants submit that claims 9 and 30 are currently amended to reflect "Lewis-y" thereby obviating the objection.

The Examiner objects to claim 12 for reciting "CHI". Applicants have amended the claim thereby obviating the rejection.

35 U.S.C. §112 Indefiniteness

The Examiner rejects claims 1-3, 5, 9, 11-13, 29, and 30 for the recitation in claim 1 of "comprising at least a part of a murine IgG2a subtype amino acid sequence." The Examiner states that the claims encompass both variable and non-variable domains including the hinge and constant domains and portions thereof. Applicants have amended claim 1 to recite "comprising a constant region of a murine IgG2a subtype amino acid sequence," thereby obviating the rejection. Applicants respectfully request that the rejection be withdrawn.

The Examiner rejects claims 2, 3, 5, 29, and 30 for the recitation in claims 2 and 3 of "or fragments thereof" stating that it is unclear whether the restriction refers to the antibody, the epitope or the tumor associate antigen of claim 2; or the antibody, the mimitope or the tumor associated antigen of claim 3. Aplicants respectfully traverse.

It is clear to one skilled in the art that the term "or fragments thereof" refers to tumor associated antigens because only a fragment of tumor associated antigen may comprise an epitope or mimitope usable to solve the problem of the present invention.

The Examiner rejects claims 9, 11, and 12 for reciting "the antigen". Applicants have amended claim 9 to provide antecedent basis and request that the rejection be withdrawn.

The Examiner rejects claim 9 for reciting "such as" because it is unclear whether the limitations following the phrase are part of the claimed invention, under MPEP §2173.05(d). The subject mater of the "such as" has been made the subject of new dependent claims 31, 32, and 33.

The Examiner rejects claims 9, 12, and 30 for improper Markush format. Applicants have amended the claims to comply with U.S. practice, thereby obviating the rejection. Applicants respectfully request the rejection be withdrawn.

The Examiner rejects claim 12 because it is unclear how "just any portion from the IgG2a sequence can be inserted into (or between) more than any one of the constant domain regions of the IgG1 antibody without affecting the binding of the acceptor antibody." Applicants have

amended claim 1, from which claim 12 depends, to recite that the antibody comprises a constant region of a murine IgG2a subtype amino acid sequence. Applicants submit that the amendment renders the claim clear, and request the Examiner withdraw the rejection.

The Examiner rejects claim 13 for the recitation of "monoclonal antibodies produced by ATCC HB 9324 or ATCC HB 9347" because a hybridoma secretes or produces full length mouse antibodies and an ATCC accession number does not. Applicants respectfully submit that one skilled in the art well understands that antibodies can be produced or expressed by hybridoma cell lines, such as those described in the instant claim. The secretion of an antibody from a cell requires that the antibody be produced, then secreted. Furthermore, the claim recites an antibody which is anti-idiotypic to the antibodies produced in the claimed hybridoma cells. Whether or not the antibody is actually secreted from the hybridoma is irrelevant. Withdrawal of the rejection is therefore requested.

The Examiner rejects claim 30 for the recitation "said carbohydrate is a number selected fro the group consisting of". Applicants have amended the claims, thereby obviating the rejection. Applicants respectfully ask that it be withdrawn.

35 U.S.C. §112 Enablement: Biological Deposit

The Examiner rejects claim 13 because the specification does not enable one skilled in the art to make and use the invention because the specification does not provide evidence that the claimed biological materials are a) known and readily available to the public or b) reproducible from the specification. Applicants respectfully traverse.

Applicants submit that the same deposits were disclosed in U.S. Patent 5,562,903, granted to inventors Co and Loibner, filed August of 1992 and granted on October 8, 1996. The patent is granted to the present inventor and refers to ATCC HB 9324 and ATCC HB 9347 as deposited on February 17, 1987 and March 10, 1987. ('903 at the section entitled "Starting Materials"). The patent discloses the deposits were made with "the American Type Culture Collection,

Rockville, Md. 20852, USA under the provisions of the Budapest Treaty." (*Id.*). Thus, the Applicants submit that the application is enabling and requests that the rejection be withdrawn.

Additionally, Applicants submit that the antibodies which are modified by the current invention are well known in the art. (*See e.g,*. WO 92/03165, US 2005/0163768). Thus one skilled in the art would be able to make and use the instant invention without undue experimentation.

35 U.S.C. §112 Enablement

The Examiner rejects claims 1-3, 5, 9, 11-13, 29, and 30 because the specification does not reasonably provide enablement for any antibody comprising "at least part of a murine IgG2a subtype sequence" or an IgG1 antibody containing any part of a murine IgG2a subtype within the constant domain which still retains antigen binding and immunogenicity. The Examiner further states that "[i]t is not well established in the art that an antibody encompassed by the claims is amenable to the extent and degree of the modifications that would allow antigen recognition and proper folding and assembly of the antibody." Applicants respectfully traverse.

Applicants submit that one skilled in the art would be able to make and use the invention without undue experimentation because the antibodies of claim 1, as currently amended, are directed to an immunogenic recombinant antibody designed for immunization of primates wherein the antibody is an IgG1 antibody wherein a constant region of said IgG1 antibody comprises a constant region of a murine IgG2a subtype amino acid sequence and a hamster or primate glycosylation. Thus the claims no longer recite "any murine IgG2a subtype region" being inserted anywhere into the instant antibody in any location.

Furthermore, the specification discloses how to make and use an epitope specific for, or a mimotope of, a TAA. The specification discloses what a TAA is. (Specification page 3, line 29-34). The specification also discloses how to create an epitope or "mimotopic antibodies against human cellular membrane antigens. . . . These antibodies are directed against the EpCAM, NCAM or CEA antigens; each of these targets is well known to be tumor associated." (Specification page 4, lines 2-6, citing EP-B1-1 140 168). Finally, the specification discloses

how to use the claimed antibodies to create a vaccine. (Specification page 15, lines 30-37). Thus Applicants submit that the one skilled in the art would understand from the disclosure how to make and use the claimed invention. Reconsideration and withdrawal of the rejection is therefore requested.

35 U.S.C. §102(b)

The Examiner rejects claims 1-3 and 29 as being anticipated by Hellstrom et al. (EP-A-0759442; published 2/26/1997).

Applicants submit that the reference does not anticipate every element of the claimed invention. In Hellstrom et al. methods for using anti-iditypic antibodies or fragments thereof for tumor immunotherapy or immunoprophylaxis are disclosed. Hellstrom relates to monoclonal anti-idiotypic antibodies mimicking human melanoma associated B97. In contrast, the immunogenic recombinant antibody according to the present invention comprises primate or hamster glycosylation and not murine glycosylation.

Applicants note that the Examiner states that "these disclosed antibodies would act in the same manner as those claimed." Applicants submit that the whether the anti-idiotypic antibodies of Hellstrom would act in the same manner as those in the instant application is speculation. Applicants submit that the specification discloses that the antibody "obtains the glycosilation pattern of the host cell, which is critical to the immunogenicity of the antibody." (Specification page 16, line 31-33). Thus Applicants submit that the reference does not anticipate the claimed invention.

Applicants additionally note that claim 11 has been incorporated into claim 1 and claim 11 was not rejected over Hellstrom. Thus Applicants respectfully submit that the amendment overcomes the rejection and request that the Examiner withdraw the rejection.

35 U.S.C. §102(e)

The Examiner rejects claims 1-3, 5, 9, 11-13, 29, and 30 as being unpatentable over Eckert et al. (US 20050163768, published July 28, 2005, with priority on some of the material to March 5, 2002). Applicants respectfully traverse.

Applicants submit that Eckert does not disclose every limitation of the instant invention; namely, that a murine IgG2a subtype amino acid sequence is introduced into the constant region of the claimed antibody.

The Examiner states that "because Eckert describes making chimeric and humanized antibodies with the BR55-2 antibodies it would be inherent to the method that one of skill in the art could also make recombinant anti-idiotypic antibodies by engineering different IgG2a regions from an anti-idiotypic antibody into an IgG1 background for example." Applicants submit that under *In re Robertson*, inherency requires that the missing element be necessarily present and that it would be so recognized by persons of ordinary skill. 169 F.3d 743, 45 (cited at MPEP 2112 (IV)). However, "the mere fact that a certain thing may result from a given set of circumstances is not sufficient." (*Id.*). Applicants submit that though Eckert generally describes making chimeric and humanized antibodies, it does not describe that a murine IgG2a subtype amino acid sequence is introduced into the constant region of IgG1 antibody. Thus Applicants submit that the invention is not anticipated by Eckert and request that the rejection be withdrawn.

CONCLUSION

In view of the above amendment, applicant believes the pending application is in condition for allowance.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact the undersigned at the telephone number below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.14; particularly, extension of time fees.

Dated: April 10, 2008

Respectfully submitted,

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